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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--|------------------------------------|
| 10/616,865 | 07/09/2003 | Martha Karen Newell | V0139.70071.US00 | 1471 |
| <div>7590 05/29/2007 Helen C. Lockhart, Ph.D. Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210</div> | | | <div>EXAMINER VANDERVEGT, FRANCOIS P</div> | |
| | | | <div>ART UNIT 1644</div> | <div>PAPER NUMBER</div> |
| | | | <div>MAIL DATE 05/29/2007</div> | <div>DELIVERY MODE PAPER</div> |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|----------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/616,865 | Applicant(s) NEWELL, MARTHA KAREN | |
| | Examiner F. Pierre VanderVegt | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 143-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 143-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/277,575, which claims the benefit of the filing date of provisional applications 60/082,250, 60/101,580 and 60/094,519.

Claims 1-142 have been canceled.

Claims 143-147 were previously added, are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's response filed August 24, 2006 the following outstanding ground of rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 143-147 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

It was previously stated: "Applicant has submitted new claims 143-147 to provoke interference proceedings with U.S. Patent No. 6,416,958. Applicant has pointed out several passages from the specification which allegedly provide support for the claimed invention, showing where each limitation is supported in the specification. While each of the individual phrases or limitations recited in the claims may indeed be supported by the asserted passages, the claims as a whole are put together in a piecemeal fashion from various portions of the specification in order to match the claimed invention of the '958 patent. However, when the instant claims are looked at in their totality, and in particular base claim 143, the claims do not enjoy written descriptive support in the specification or claims as originally filed. The claims as presented are a patchwork of phrases which have been drawn from various passages in the specification, but these passages are never found in a single cohesive concept. Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, the claimed embodiment of claim 143 may be obvious when individual passages from the specification are brought together, but the claim as a single concept is not supported by the specification or claims as originally filed. Accordingly, the claims do not have written descriptive support in the specification or claims as originally filed and constitute new matter.

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Applicant's arguments filed March 8, 2007 have been fully considered but they are not persuasive. Applicant argues that the claimed invention enjoys full written descriptive support from original claim 8, which is dependent upon base claim 1 through claims 4 and 3. Applicant's assertion fails to overcome the ground of rejection.

Instantly pending claim 143 broadly recites a method of inducing the death of HLA-DR-expressing tumor cells by administering to a subject a therapeutically effective amount of an anti-HLA-DR antibody. The claim reads upon any exposure of a tumor cell to an anti-HLA-DR antibody that results in cell death, irrespective of the mechanism. The claim is inclusive, for example, of anti-HLA-DR antibodies that cause cell death by targeting a toxin to the cell or by the fixation of complement to the cell.

Original claim 8 is also drawn to the therapeutic exposure of tumor cells to an anti-HLA-DR antibody; however, the claim is narrowly drawn to a specific mechanism.

Original base claim 1 recites a method for decreasing mitochondrial membrane potential in a mammalian cell by engaging an HLA-DR molecule on the surface of the cell with a **ligand** of the HLA-DR molecule in an amount effective to decrease mitochondrial membrane potential. In other words, the binding agent must be a molecule to that the HLA-DR molecule is a specific receptor for. The agent must be one that is specifically recognized by and binds into the antigen-binding groove of the HLA-DR molecule. The claim does not read upon any agent that binds to any other part of the HLA-DR molecule. Furthermore, claim 1 recites that the target cell cannot be an antigen-presenting cell (APC).

Original claim 3 adds the limitation that the cell must be contacted with an HLA-DR inducing agent effective to induce the expression of HLA-DR on the cell. Therefore, this claim reads upon cells that do not constitutively express HLA-DR.

Original claim 4 adds the further limitation that the mammalian cell is a tumor cell and that the exposure to the **ligand** of the HLA-DR molecule in an amount effective to decrease mitochondrial membrane potential takes place *in vivo*. Claim 4 also limits the inducing agent to exclude Adriamycin and gamma interferon.

Original claim 8 adds the further limitation that the **ligand** of the HLA-DR molecule that decreases mitochondrial membrane potential is an anti-HLA-DR antibody.

Accordingly, claim 8 of the instant specification as originally filed reads only upon a method of using an antibody to HLA-DR that specifically binds to the binding groove of a HLA-DR molecule and that induces lysis of a tumor cell that has been induced to express HLA-DR with an inducing agent that is

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not Adriamycin or gamma interferon, wherein said lysis of the tumor cell takes place by the mechanism of decreasing mitochondrial membrane potential in the tumor cell.

In contrast, currently pending non-original claim 143 reads upon a method of inducing tumor cell death by administering an effective amount of any anti-HLA-DR antibody, wherein the anti-HLA-DR antibody can bind to any determinant on an HLA-DR molecule on any tumor cell, even one that is an APC, that expresses HLA-DR, whether that expression has been induced or not even if an induction was mediated by Adriamycin or gamma interferon, and wherein the death of the tumor cell takes place by any means under the sun that can result from an antibody-containing agent binding to the tumor cell.

Contrary to Applicant's position, the combination of original claims 1, 3, 4 and 8 drawn to a narrow method for the killing of tumor cells does not provide adequate written descriptive support for the broadly recited method of killing tumor cells of currently pending non-original claims 143-147.

Conclusion

2. No claim is allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. 
Patent Examiner
May 24, 2007



DAVID A. SAUNDERS
PRIMARY EXAMINER